DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 10, 2015

Medovations, Inc.
Laura Boll
Vice President of Quality and Regulatory Affairs
102 East Keefe Avenue
Milwaukee, WI 53212

Re: K142068
Trade/Device Name: Medovations BullDog® Biopsy Valves
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: January 30, 2015
Received: February 2, 2015

Dear Laura Boll,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142068

Device Name
Medovations BullDog® Biopsy Valve

Indications for Use *(Describe)*
The single use BullDog® Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® and Fujinon® or Pentax® gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

1. Submission Sponsor

Submitter's Name:	Medovations
Submitter's Address:	102 E. Keefe Ave Milwaukee, WI 53212
Establishment Registration No.:	2183446

2. Sponsor Contact

Contact Person:	Laura Boll Director of Quality and Regulatory Affairs
Telephone:	414-755-4806 (direct) 414-265-7620 ext. 4806
Email:	lboll@medovations.com

2. Date Prepared

July 21, 2014
Revised January 27, 2015 - revise classification from ODC to OCX per FDA response

3. Device Identification

Trade Device Name:	Medovations BullDog® Biopsy Valve
Common Device Name:	Biopsy Valves
Classification Name:	OCX - Endoscopic Irrigation/Suction System
Regulation Number:	21 CFR 876.1500

4. Predicate Device Identification

Predicate Device 510(k) No.:	K070420
Predicate Device Trade Name:	US Endoscopy BioShield® ERCP Biopsy Valve
Predicate Device Product Code:	KOG

5. General Device Description:

The Medovations Disposable Biopsy Valve is a single piece construction of molded thermoplastic elastomer. The biopsy valve has a cylindrical body with an open inner diameter for device passage. This cylindrical body has a connected cap with a slit to

allow for endoscopic device passage and exchange, to help maintain sufflation, to minimize leakage of biomaterial from the biopsy port throughout endoscopic procedures, and to provide access for irrigation.
The distal part of the biopsy valve body is molded to fit the biopsy/suction channel of the endoscope. The proximal part of the biopsy valve body is molded to fit around the cap when it is in the closed position.

The Medovations Disposable Biopsy Valves are manufactured in two configurations - one for use with Olympus®/Fujinon® gastrointestinal endoscopes and the other for use with Pentax® gastrointestinal endoscopes. The Olympus®/Fujinon® versions are sold as both sterile and non-sterile devices. The Pentax® version is sold non-sterile.

The Irrigating Adaptor accessory is comprised of a metal tube with standard luer lock and can be used with the biopsy valve to provide access for irrigation.

6. Intended Use:
The single use Medovations BullDog® biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus® and Fujinon® or Pentax® gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

7. Technological Characteristics
The following table is a summary of the Medovations Biopsy Valve technological characteristics as compared to the predicate device from US Endoscopy.

Table 5.1 Summary of design, features and principles of operation between the Medovations BullDog® Biopsy Valve and Irrigating Adaptors and Predicate Device US Endoscopy BioShield® Biopsy Valves and Irrigating Adaptors

Characteristic	Medovations	US Endoscopy
Trade Name	BullDog® Biopsy Valves	BioShield® ERCP Biopsy Valves
510(k) Number	K142068	K070420
Product Code	OCX	KOG
Regulation Number	876.1500	876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Manufacturing Design	Single piece injection molded	Single piece injection molded
Material	Thermoplastic elastomer	Thermoplastic elastomer

Characteristic	Medovations	US Endoscopy
Endoscope Compatibility	Molded versions to fit biopsy/suction channel of Olympus/Fujinon gastrointestinal endoscopes or biopsy/suction channel of Pentax gastrointestinal endoscopes	Molded versions to fit biopsy/suction channel of Olympus/Fujinon gastrointestinal endoscopes or biopsy/suction channel of Pentax gastrointestinal endoscopes
Valve Body Minimum Inner Diameter	.065"	.065"
Removable Cap with Slit for Device Passage	Yes	Yes
Intended Use	The single use Medovations BullDog® biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and Fujinon (G5 series and newer) gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.	The single use BioShield® - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.
Environment	Hospital, Ambulatory Surgery Center, or Clinic	Hospital, Ambulatory Surgery Center, or Clinic
Patient Population	Device has no direct patient contact and is used on any patient undergoing endoscopy	Device has no direct patient contact and is used on any patient undergoing endoscopy
Patient Contact Categorization	No direct patient contact. Indirect patient contact from devices and/or irrigating solution that is in contact with the biopsy valve and accessory irrigating adaptor.	No direct patient contact. Indirect patient contact from devices and/or irrigating solution that is in contact with the biopsy valve and accessory irrigating adaptor.
Sterile	Sterile and non-sterile versions available of the Olympus/Fujinon Style Non-Sterile version of the Pentax Style	Sterile and non-sterile versions available of the Olympus/Fujinon Style Non-Sterile version of the Pentax Style
Sterilization method	EO gas	EO gas

Characteristic	Medovations	US Endoscopy
Single Use, Disposable	Yes	Yes
Shelf Life	3 years	3 years
Accessory Device	Irrigating Adaptor comprised of a hollow metal tube with standard plastic luer lock connector	Irrigating Adaptor comprised of a hollow metal tube with standard plastic luer lock connector

8. Non-Clinical Performance Data

Medovations performed bench testing to support substantial equivalence. The following testing was performed on Medovations samples from initial production lots, including sterilization (where applicable):

a. Fluid Flush Performance - Fluid flush was simulated by inserting the irrigating adaptor into the biopsy valve slit and injecting water through the irrigating adaptor to confirm there is no fluid backsplash onto the user during a fluid flush. This test was performed on both the Medovations Biopsy Valve and Irrigating Adaptor and the predicate US Endoscopy Biopsy Valve and Irrigating Adaptor. The Medovations Biopsy Valve performed as well as the predicate device and there was no evidence of fluid backsplash during this simulated use testing.

b. Leak testing - Leak testing was performed to demonstrate sufflation is maintained during use and leakage is minimal when devices are passed through the biopsy valve. This testing put the biopsy valves under a vacuum and measured the vacuum being held by the biopsy valve both with and without a device passing through the slit. This test was performed on both the Medovations Biopsy Valve and the predicate US Endoscopy Biopsy Valve. The Medovations Biopsy Valve performed as well as or better than the predicate device in maintaining applied vacuum pressures both with and without a device passing through the slit.

c. Compatibility with Endoscope - Compatibility of the biopsy valve with the designated endoscope was tested by placing the biopsy valve on the biopsy/suction channel of the appropriate endoscope (either Olympus or Pentax). The fit was confirmed visually through a series of opening and closing of the attached cap to simulate the stresses during use. The Medovations Biopsy Valve performed as well as the predicate device in remaining seated on biopsy/suction channel of the designated endoscope through this series of simulated use movements.

d. Squeegee Performance - The ability of the biopsy valve to squeegee off materials was tested by coating a biopsy forceps with mustard and then pulling that biopsy forceps back through the biopsy valve. The amount of mustard remaining on the forceps after passage through the biopsy valve was visually evaluated. This test was performed using both the Medovations Biopsy Valve and the predicate device. The Medovations Biopsy Valve visually performed as well as the predicate device in removing materials from a device passing through it.

e. Sterilization - The Olympus/Fujinon compatible biopsy valve is sold in both sterile and non-sterile options, like the US Endoscopy predicate device. The sterile option has been sterilized in a validated EO sterilization cycle. The EO sterilization cycle has a Sterility Assurance Level (SAL) of 10^{-6}. EO residuals on the biopsy valves are below the maximum levels defined in ANSI/AAMI/ISO 10993-7:1995 *Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide sterilization residuals.* The Medovations biopsy valves, and the predicate devices, are not labeled as pyrogen-free because they do not have any blood or cerebrospinal fluid contact. The Medovations biopsy valves are packaged in a paper/film pouch like other sterile products Medovations currently manufactures. These pouches have been tested by Medovations, including simulated distribution stresses and real-time aging, and shown to provide and maintain a sterile barrier for at least five (5) years.

f. Shelf Life - The Medovations Biopsy Valves have a three (3) year expiration date, based on the design and material equivalence to the predicate device and existing sterile barrier data from Medovations existing packaging. The Medovations biopsy valves are packaged in a paper/film pouch like other sterile products Medovations currently manufactures. These pouches have been tested by Medovations, including simulated distribution stresses and real-time aging, and shown to provide and maintain a sterile barrier for at least five (5) years.

9. Clinical Testing

Biopsy valves have been on the market for many years with proven safety and efficacy for the use of the device. These devices have no direct patient contact. Based on this history and the use of the device, clinical testing was not necessary to support substantial equivalence data. The non-clinical testing performed supports safety and efficacy of the device and provides data to show substantial equivalence to the predicate device.

10. Conclusion

Medovations biopsy valves have the same intended use as the predicate device. Based on the technological characteristics and overall performance of the devices in bench testing, Medovations believes that no significant differences exist between the proposed biopsy valve and the predicate device.
The Medovations biopsy valves do not raise any new issues of safety and effectiveness. From a clinical perspective and comparing design specifications, the Medovations biopsy valve and the predicate device are substantially equivalent.